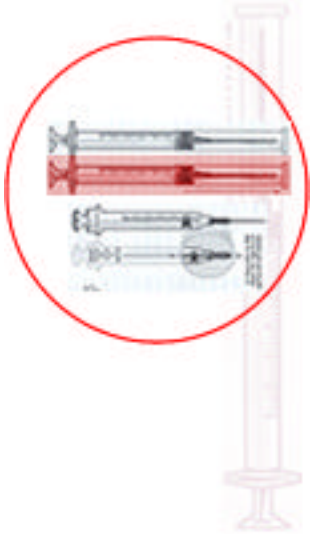
NIOSH recommends that health care facilities use safer medical devices to protect workers from needlestick and other sharps injuries. Since the passage of the Needlestick Safety and Prevention Act in 2000 and the subsequent revision of the OSHA Bloodborne Pathogen Standard, all health care facilities are required to use safer medical devices.

SAFER MEDICAL DEVICE IMPLEMENTATION IN HEALTH CARE FACILITIES

SHARING LESSONS LEARNED

NIOSH has asked a small number of health care facilities to share their experiences on how they implemented safer medical devices in their settings. These facilities have agreed to describe how each step was accomplished, and also to discuss the barriers they encountered and how they were resolved, and most importantly, lessons learned.



This free-standing, not-for profit, 300+ bed hospital is accredited by JCAHO and offers acute and subacute inpatient care, including a cardiac center, cancer center, rehabilitation unit, skilled nursing facility, and residential hospice. The wide range of outpatient and community outreach programs includes home health care, hospice, adult day care, community health screenings, occupational health, and a health education center. 450 physicians on staff represent more than 20 medical specialties and the organization employs 2000+ health care workers.

Phase 3 - Identify and Screen Safer Medical Devices

Step 1 - Identify the Manufacturer and Their Products

As the sharps safety education program (previously mentioned) was presented to the clinical departments at their work sites, the staff identified the sharps used in their work areas and the work procedures that they felt were a threat to their personal safety, which could be improved. This staff information was collated with the employee injury data that had already been reviewed by the Sharps Taskforce, who then developed a priority list of safe medical devices to be screened and evaluated. Each taskforce member agreed to facilitate the identification and evaluation process for a sharps safe device.

One of the hospital purchasing agents was the key staff member who assisted the taskforce in the identification of vendors for safe medical devices. The purchasing agent issued requests for information proposals (RFPs) on safe medical devices to all the vendors in the hospital group purchasing management contract. Hospital clinical staff and directors also communicated to the taskforce members their own management needs and concerns.

The initial safe medical devices that were identified were:

- arterial blood gas kits
- disposable safety scalpels (for minor procedure trays)
- products for IV catheter needleless blood draws
- sharps safe disposal containers
- sharps safe IM/IV syringes

An administrative policy and procedure ("Safety - Sharps Safety Medical Product Clinical Evaluation") was developed by the taskforce and approved by the Safety and Environment of Care Committee and administrative staff. This policy and procedure is an attachment to this report.

Step 2 - Examining the Devices to Ensure Appropriateness to Setting

The purchasing agent sent the identified vendor names, sample devices, and device information to the Chair and Co-Chair of the taskforce for review and consideration. The medical information obtained from the vendors included brochures, pamphlets, videotapes, and user lists. There was also direct taskforce interaction with some of the sales representatives, who were invited to interactive presentations at the taskforce meetings, during the device review process.

Evaluation assessment criteria were developed from the literature search documents to use in the screening of the safe medical devices:

- The effect of the product on clinical techniques
- The security of the locking mechanism
- How easy it is to lock the safety mechanism
- The reliability of the locking mechanism
- The level of safety provided by the safety mechanism
- The ease of teaching how the product should be used
- The safety feature should allow or require the health care worker's hands to remain behind the sharp as it is covered
- The cost/benefit of the device

The taskforce then communicated recommendations to pilot test the safer medical devices to the responsible department director. The director reviewed the taskforce recommendation with their staff, practicing physicians in their work areas, and their medical director(s) to discern their opinions and ask for their support. The taskforce members worked with the department directors to answer any questions that revealed concerns by staff and physicians.

The Sharps Taskforce was given total authority and responsibility for the identification and screening of safer medical devices by hospital administration.

What Lessons Were Learned

1. It is necessary to assign both a taskforce facilitator and a staff member from the trial area to coordinate the steps and develop and manage the documentation required for the trial.

2. Frequent and consistent communication to the department director/manager and medical staff regarding anything involving their practice areas is needed to ward off any resistance and misunderstandings.

3. All communication with staff highlighted the personal benefits attained in creating a sharps safe work environment.

4. A centralized purchasing system is necessary in order to encompass all sharps products/devices entering the hospital system. The purchasing agents are key to monitoring this area.

What We Would Do Differently

Initially, only a taskforce member was assigned to coordinate the pilot testing of the safe medical device. This resulted in incomplete evaluation documentation and lack of pilot testing ownership by the clinical staff. Subsequently, pilot testing coordination included both a taskforce member and a clinical staff member who coordinated the process for their work area: staff education, evaluation forms, and feedback.

Recommendations

1. Include information on sharps safety and the Sharps taskforce in all new employee orientation and annual safety education.

2. Find a sharps safety champion at the administrative level of your organization.

Time Spent in Identifying and Screening Safer Medical Devices

It is almost impossible to put a numeric value on the time spent in this phase of implementation because of all the events and tasks that were occurring at the same time along with the number of staff members who were involved.

A-1012/01

ADMINISTRATIVE POLICIES AND PROCEDURES

SUBJECT: **Safety - Sharps Safety Medical Product Clinical Evaluation**

EFFECTIVE DATE: October, 2001

INTENT

To identify the process for a medical product clinical evaluation for sharps and to insure organizational compliance with the OSHA Bloodborne Pathogens directive.

DEFINITIONS

OSHA: Occupational Safety and Health Administration

POLICY

The Sharps Safety Medical Product Clinical Evaluation will be completed as new clinical sharps safe medical devices are being considered for purchase.

PROCEDURE

1. The Sharps Taskforce will accept and review all requests for the trial of sharps safety products.
2. Requests for a trial of sharps safety products must include the following:
   a. The name of the lead investigator.
   b. A listing of product usage by location and recommended trial locations.
   c. Identification of the evaluation assessment criteria to be used during the trial/evaluation period. The "Medical Product Clinical Evaluation" form is to be used as a template to tailor specific product trial evaluation forms.
3. The lead investigator for the trial is responsible for:
   a. Coordination of the trial and completion of all evaluation forms.
   b. Communicating status and outcome of the trial to the Sharps Taskforce.
4. The Sharps Taskforce will make recommendations to the pertinent departments and the Safety Committee regarding new clinical sharps safety medical devices.

REVIEW DATE(S):

REVISION DATE(S):

SUPERSEDES:

APPROVED BY: President & C.E.O.
DATE APPROVED: 10/11/01

PRIMARY RESPONSIBILITY: Safety and Environment of Care Committee

CROSS-REFERENCE TO: The Infection Control Manual

KEY WORDS: sharps, safety, products, criteria, trail, evaluation

ADDENDUM(S): N/A

FORM AVAILABILITY: The "Sharps Safety Medical Product Clinical Evaluation Form"

Sharps Safety Medical Product Clinical Evaluation Form

Product Description:

Manufacturer Name:

Catalog Number:

Lead Investigator:

Trial Location/Contact Person in Trial Location/Phone Number:

Trial Date(s):

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* Evaluation Assessment Criteria:

1. The effect of the product on clinical technique.
2. The security of the locking mechanism
3. How easy it is to lock the safety mechanism.
4. The reliability of the locking mechanism.
5. The level of safety provided by the safety mechanism.
6. The ease of teaching how the product should be used.
7. The safety feature should allow or require the HCW's hands to remain behind sharp as it is covered.
8. The safety feature should be an integral part of the device
9. The safety feature should remain activated during disassembly and disposal.
10. The safety feature should be simple and require little or no user action or training.

* These criteria are to be used to develop product specific detailed criteria for a trial.